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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,320	02/13/2001	Bernhard H. van Lengerich	BVL-102A	9819

7590 11/23/2010

Douglas J. Taylor, Esq.
General Mills, Inc.
P.O. Box 1113
Minneapolis, MN 55440

EXAMINER	
ROBERTS, LEZAH	
ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
11/23/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/782,320	VAN LENGERICH, BERNHARD H.	
	Examiner	Art Unit	
	LEZAH W. ROBERTS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *94* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-31,34,35,37-40,42,46,50,52-59,61,62,64-67,69,70,73,75,79,81-85,91-93, 95-97,101,103,105 and 108-110* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 25-31,34,35,37-40,42,46,50,52-59,61,62,64-67,69,70,73,75,79,81-85,91-97,101,103,105 and 108-110.

DETAILED ACTION

Applicants' arguments, filed August 18, 2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 112 – Written Description (Previous Rejection)

Claims 31, 59, 108 and 109 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is maintained.

Applicant's Arguments

Applicant argues that the term "'derivative" is used extensively in the USPTO class definitions as exemplified by a search in the USPTO online Manual of Classification for the term "derivative". Applicants submit that the polyvinyl acetate derivatives and modified starches claimed are conventional, well known components to those ordinarily skilled in the art. Further, as the terminology utilized in the pending claims that the Examiner finds improper or unsupported by the original disclosure is standard patent parlance fully supported under the U.S. Patent and Trademark guidelines, Applicants submit that one ordinarily skilled in the art would readily understand how to make and use the claimed encapsulated products using the claimed polyvinyl acetate derivatives and modified starches, even without express disclosure of all possible species of polyvinyl acetate derivatives and modified starches in Applicants' disclosure.

Examiner's Response

Applicant does not provide any example of what is included by the term "derivative". Although derivatives are used in classification, this does not however, support that Applicant has written description for the term "derivative", and all that term encompasses. Therefore one of skill in the art would not readily know what "derivatives" are encompassed by Applicant's recitation of "polyvinyl acetate derivative" or if

Applicant had possession of any polyvinyl acetate derivatives at the time the invention was made. Further, there are no examples provided as to what is encompassed by this term in such a way that would apprise one to know what compounds are encompassed by Applicant's of derivatives and modified starches and when a compound is modified to a degree where it is no longer considered a derivative or modified compound of the parent compound. Thus, the instant specification is unclear and does not define at what point modifying the core compound lead to different compounds that would not be considered a derivative encompassed by the instant invention.

Claim Rejections - 35 USC § 112 – Indefiniteness (Previous Rejection)

Claims 31, 59, 108 and 109 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is maintained.

Applicant's Arguments

Applicant argues the rejection of claims 31, 59, 108, and 109 under 35 U.S.C. 112, second paragraph, because of use of the term "'derivative" is untenable for reasons as given above with respect to the rejection under the first paragraph of 35 U.S.C. 112. As discussed above, the term "derivative" is well known to those skilled in the art as exemplified by the extensive use of the term in the USPTO class definitions. Additionally, the terms are well known as further exemplified by Newton et al (USP 4,938,967) at col. 8 lines 61-65, and col. 9 lines 18-29, and Wittwer et al (USP

4,738,724) at col. 7 line 67 to col. 8 line 24.

Examiner's Response

As previously asserted in the previous Office Action, although polyvinyl acetate is definite, the term derivative is not. The term "derivative" is indefinite because it is unclear how far one can deviate from the parent compound without the "derivative" being so far removed therefrom as to be a completely different compound. Further, Applicant does not appear to provide any examples as to what compounds "derivatives" encompass. Additionally, based on the instant specification, it is also not clear what "derivatives" are suitable for use in the instant invention. See the Examiner's Response in the "Written description" section supra.

Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)

1) Claims 25-31, 34, 35, 37-40, 46, 50, 52-59, 61, 62, 64-67, 73, 75, 79, 81-83, 85, 91, 92, 93, 95-97, 101, 103, 105, 108 and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newton et al. (4,938,967) in view of Eden et al. (US 4,755,397).

Newton et al. disclose pharmaceutical compositions. The dosages are preferably capsules that contain one or more units. Density of conventional tablets and pellets is usually about 1.0 to 1.5 g/ml (1000 to 1500 g/liter) (col. 1, lines 11-13), encompassing claim 34. Selection of the binder determines the rate of release of the active ingredient (col. 1, lines 19-21). The dosage may be a plurality of pellets having a dimension below

about 2 mm, encompassing claims 28 and 55. The pellets have a shape that is spherical (col. 7, lines 48-57). The active ingredient comprises 0.0001 to 45% of the compositions (col. 10, lines 30-35). Various active agents may be used such as tonics (encompassing claim 93), anti-inflammatory, enzymes and anti-viral agents (col. 13 to col. 14, line 48). The pellets may comprise a matrix binder and a coating. These serve to control the release of the active. Binders include polymers such as starch and cellulose (col. 8, lines 53-68). Generally water is added to the compositions to aid in pelletisation (col. 11, lines 37-39), encompassing a water plasticizer. The matrix binder may comprise 50% of the particles (col. 10, lines 22-25). Each pellet may comprise a homogeneous blend of the active, the weighing material and the matrix binder components (col. 10, lines 58-60). Magnesium stearate also may be added to the compositions (Example 3), encompassing claims 31 and 59.

The reference differs from the instant claims insofar as it does not disclose the exact amounts of matrix material or encapsulant as recited in the instant claims and does not disclose the starch is plasticized by heating.

Eden et al. disclose a wide range of materials may be encapsulated in a starch matrix by combining the material with a high temperature-stabilized pressurized dispersion of starch in the presence of salt. The starch acts as a protective colloid and the composition is particulate form (Abstract). Materials include flavoring oils, pigments oils, plasticizers, herbicides, insecticides, bacteriocides, drugs, vitamins and enzymes. These materials comprise 0.1% to 80% of the starch matrix. (col. 1, line 63 to col. 2, line 12). The starch is mixed with water and the starch comprises 5 to 40%. Starches

include corn starch, rice starch potato starch and wheat starch. The starch may be used in modified or unmodified form (col. 2, lines 13-56). The starches used include those with high amylase content (col. 2, lines 35-37) the starch may also be already cooked, encompassing claims 26 and 53. Additional polymers include polyacrylic acid and polyvinyl pyrrolidone (col. 2, lines 23-27) encompassing claims 50 and 79. The compositions are heated to 120 to 180 degrees C. This forms a mass where the encapsulated material is uniformly dispersed. Examples of salts include ammonium sulfate and magnesium sulfate (col. 2, lines 28-30).

The reference differs from the instant claims insofar as it does not disclose the amount of pharmaceutical that may be added to the compositions, the amount of the composition in the final product or the size of the granules made from the composition.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art to have used a heated plasticized starch matrix in the formulations of Newton et al. motivated by the desire to use a composition that is temperature stabilized and provides a protective colloid to the active material, as disclosed by Eden et al and supported by MPEP 2144.07.

It would have been obvious to have coated the actives before incorporating them into the matrix of Eden et al. motivated by the desire to add an additional control release mechanism for the active agent as suggested by the teachings of Newton et al.

Newton et al. disclose the active may comprise 0.0001 to 45% of the compositions. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Therefore it would have been obvious to have used 1 to 85%, 5% to 50%, 3% to 50% and 5% to 20% of encapsulant (active agent) consistent with the In re Peterson decision.

In regards to the amounts recited in the instant claims such as the amount of matrix material, this is a result effective variable. The matrix material controls the release of the active and the active results in achieving the desired effect for the desired treatment. That being said, it would take no more than routine skill in the art to adjust the amount of matrix binder in the pellets to achieve the desired active release profile including the amount of active released in an aqueous or gastric juice environment as recited in claims 38 and 65.

Eden et al. disclose temperature ranges from 120 to 180 degrees C (col. 3, lines 3-8) similar to those disclosed by the instant specification up to 160 degrees C. Thus it is reasonable to conclude that the starches used by Eden et al. are not "substantially dextrinized".

2) Claims 42, 69, 70, 84 and 108-110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newton et al. (4,938,967) in view of Eden et al. (US 4,755,397) as applied to claims 25-31, 34, 35, 37-40, 46, 50, 52-59, 61, 62, 64-67, 69, 73, 75, 79,

81-83, 85, 91, 92, 93, 95-97, 101, 103, 105, 108 and 109 in further view of Jane et al. (US 5,397,834).

Newton et al. and Eden et al. differ from the instant claims insofar as they do not disclose the wheat used as a starch source is durum wheat.

Jane et al. disclose biodegradable thermoplastic components made of the reaction of a starch aldehyde with protein. Suitable starches include those derived from durum wheat (col. 4, lines 41-50). The reference differs from the instant claims insofar as it does not disclose the thermoplastic compositions are formulated into discrete particles comprising an active agent.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art to have used wheat durum as the wheat in the compositions of the combined teachings of Newton et al. and Eden et al. motivated by the desire to use a wheat comprising starch suitable for making thermoplastic compositions as disclosed by Jane et al. and supported by MPEP 2144.07.

Claims 25-31, 34, 35, 37-40, 42, 46, 50, 52-59, 61, 62, 64-67, 69, 70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103, 105 and 108-110 are rejected.

Claim 94 are withdrawn.

No claims allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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/Lezah W Roberts/
Examiner, Art Unit 1612

/Gollamudi S Kishore/
Primary Examiner, Art Unit 1612